510(k) Summary

Submitter Name:	GMV Aerospace and Defence S.A.
Submitter Address:	Isaac Newton, 11; PTM Tres Cantos Madrid 28760 Spain
Phone Number:	011 34 91 807 22 70
Fax Number:	011 34 91 807 21 99
Contact Person:	Carlos Illana Alejandro
Date Prepared:	15 July 2011
Device Trade Name:	radiance
Common Name	Radiation Treatment Planning Software
Classification Name, Number & Product Code:	Medical charged-particle radiation therapy system 21 CFR 892.5050 MUJ
Predicate Devices:	RayStation K100552 cleared 12 March 2010
Device Description and Statement of Intended Use	radiance is a treatment planning system, that is, a software program for planning and analysis of radiation therapy plans. Typically, a treatment plan is created by importing patient images obtained from a CT scanner, defining regions of interest either manually or semi-automatically, deciding on a treatment setup and objectives, optimizing the treatment parameters, comparing alternative plans to find the best compromise, computing the clinical dose distribution, approving the plan and exporting it. Statement of Intended Use: *radiance is a software system intended for treatment planning and analysis of intraoperative radiation therapy by means of electron beams.* *The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed*

treatment, and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

The intended users of radiance shall be clinically qualified radiation therapy staff trained in using the system.

Summary of Technological Characteristics	The technological characteristics are essentially the same as those of the predicate. All devices produce treatment plans with corresponding dose distributions computed using a three dimensional dosimetry engine. All devices have a function of electronic approval of treatment plans by trained and authorized staff, and export in DICOM format for commencing treatment or archiving.
Substantial Equivalence	The radiance device is substantially equivalent to the RayStation (K100552), with respect to technical and design features. The submitted devices pose the same types of questions about safety or effectiveness as the existing device.
Conclusion	The information discussed above demonstrates that the radiance device is substantially equivalent to the predicate device.
Declarations	o This summary includes only information that is also covered in the body of the 510(k). o This summary does not contain any puffery or unsubstantiated labeling claims. o This summary does not contain any raw data, i.e., contains only summary data. o This summary does not contain any trade secret or confidential commercial information. o This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Device radiance	RayStation	Eclipse	NOVAC7
510(k) Number		K100552	K102011	K990209
Manufacturer	GMV Aerospace and Defence S.A.	RaySearch Laboratories AB	Varian Medical Systems, Inc.	HITESYS S.P.A.
Classification # & Product Code	21 CFR 892.5050 MUJ	21 CFR 892.5050 MUJ	21 CFR 892.5050 MUJ	21 CFR 892.5050 IYE
Intended Use	radiance is a software system intended for treatment planning and analysis of intraoperative radiation therapy by means of electron beams. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs. The intended users of radiance shall be clinically	RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs. The intended users of RayStation shall be clinically qualified radiation therapy	The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, **electron** and proton beams, as well as for internal irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.	The NOVAC7 is an electron linear accelerator used for radiation therapy during surgical procedures in an operating room for the treatment of malignant and benign conditions. Know as intraoperative radiation therapy (IORT), this technique allows delivery of high doses of radiation directly aimed at tumors or other sites while avoiding dosage to surgically mobilized normal tissues. The NOVAC7 is a mobile and articulated machine that can be moved towards the patient and put in the appropriate position to carry out the necessary radiotherapy. Applicators direct the electron beam to the surgical area of interest

	qualified radiation therapy staff trained in using the system.	staff trained in using the system.		
System Design	Software only	Same	Software only	Hardware and Software
Calculation	Dose distributions computed using a three dimensional dose engine.	Same	Same for electrons	Same for MU computation
Input	Externally acquired patient medical images and user input	Same	Same	Same for MU: MU/Gy factor + additional factors
Output	Treatment plans with corresponding dose distributions	Same	Same for electrons	Monitor units
Plan review and approval	Allows electronic approval of treatment plans by trained and authorized staff	Same	Same	None
Dose calculation algorithm confirmation	Algorithms confirmed for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings.		Same for electrons	Same for MU computation

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN - 6 2012

GMV Aerospace and Defence S.A.
% Mr. William F. Greenrose
Official Correspondant and Regulatory Consultant for GMV Aerospace and Defence S.A.
Qserve America, Inc.
220 River Road
CLAREMONT NH 03743-5647

Re: K112060
Trade/Device Name: radiance
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: December 8, 2011
Received: December 13, 2011

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112060

Device Name: **radiance**

Indications For Use:

radiance is a software system intended for treatment planning and analysis of intraoperative radiation therapy by means of electron beams.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

The intended users of radiance shall be clinically qualified radiation therapy staff trained in using the system.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112060